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10/049,727	06/25/2002	Yahia Gawad	3477.93	4559

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MYERS BIGEL SIBLEY & SAJOVEC
PO BOX 37428
RALEIGH, NC 27627

EXAMINER	
FOSTER, CHRISTINE E	

ART UNIT	PAPER NUMBER
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/049,727	GAWAD ET AL.	
	Examiner	Art Unit	
	Christine Foster	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) *25-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-24* is/are rejected.

7)☒ Claim(s) *2-13, 16-17, 19, 21, and 23* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/13/02, 9/18/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II, claims 1, 3, 5, 8-9 and 13-24 in the reply filed on November 21, 2005 is acknowledged. The traversal is on the ground(s) that the claims do form a single general inventive concept since all of the claims recite methods and compositions for determining PAI-1 in a biological fluid. This is not found persuasive because the record as clearly set forth in the previous office action shows that this feature cannot be considered to be a special technical feature since it does not represent a contribution over the prior art (see p. 3 of the Office Action mailed September 20, 2005). Applicant also argues that Group V should be examined together with Group II since Group V recites a kit for carrying out the method of Group V. This argument is not persuasive in light of the lack of unity finding discussed above.

The requirement is still deemed proper and is therefore made FINAL.

Upon reconsideration, the Examiner has rejoined Groups I (claims 1, 3, 5, 8-9, and 13-24) and III (claims 1, 10-11, and 14-24) with Group II. Consequently, claims 1-24 are currently under examination. Claims 25-33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Applicant's amendment filed 11/21/05 is acknowledged and has been entered. Claims 1-33 are pending, with claims 25-33 currently withdrawn.

Information Disclosure Statement

Applicant's Information Disclosure Statements filed August 13, 2002 and September 18, 2002 have been received and entered into the application.

The information disclosure statement filed September 18, 2002 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; **each non-patent literature publication or that portion which caused it to be listed**; and all other information or that portion which caused it to be listed. Copies of the non-patent literature documents were not received. The information disclosure statement has been placed in the application file, but the information referred to therein has not been considered unless so indicated on the attached forms PTO-1449 or PTO-892.

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

2. The disclosure is objected to because of the following informalities: on p. 11, line 24, the specification refers to a publication by "Sockman et al." that includes the year, volume, and pagination information for the publication but not the name of the journal in which the publication may be found. Applicant appears to be referring to a publication by Stockmann et al. in the Journal of Biological Chemistry. It is requested that the specification be amended to include the full and correct reference.

Appropriate correction is required.

Claim Objections

3. Claims 2-13, 16-17, 19, 21, and 23 are objected to because of the following informalities:

4. Applicant is requested to use a consistent spelling of the word "labeled" (either "labeled" or "labelled") in the claims.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. Claims 1-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for determining active PAI-1 in serum, plasma, platelets, or platelet releasates, does not reasonably provide enablement for determination in all biological fluid samples. The specification does not enable any person skilled in the art to which it pertains, or

with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The nature of the invention is a sandwich-type ELISA immunoassay to detect a complex of PAI-1 with multimeric vitronectin using antibodies to each of PAI-1 and multimeric victronectin.

The claims encompass detection of the PAI-1/multimeric vitronectin complex in any biological fluid, and the specification discloses that such fluids to be assayed include whole blood, plasma, serum, saliva, amniotic fluid, cerebrospinal fluid, tissue extract, and urine (p. 7, lines 18-20).

The prior art teaches that vitronectin is a plasma protein, and it has been detected in complex with PAI-1 in platelet-rich plasma samples as well as in platelet releasates (see Preissner et al. (*Blood* **74**:1989-1996 (1999), p. 1989, the first paragraph and p. 1990-1991, the sections "Platelet preparation and aggregation" and "Quantitation of platelet vitronectin"; and p. 1995, right column). The component protein vitronectin is known to be expressed in platelet releasate, plasma, and serum (see Stockmann et al., "Multimeric Vitronectin: Identification and Characterization of Conformation-Dependent Self-Association of the Adhesive Protein," *J. Biol. Chem.* **268**:22874-22882, 1993, at p. 2876, left column, "Results").

The prior art fails to teach that the PAI-1/multimeric vitronectin complex is expressed and may be detected in saliva, amniotic fluid, cerebrospinal fluid, tissue extract, or urine. Similarly, the complex has not been detected in extracts of tissue, other than platelet releasates (which are extracted from blood tissue).

The specification discloses only prophetic examples, such that there are no working examples of detection of active PAI-1 in saliva, amniotic fluid, cerebrospinal fluid, tissue extract, or urine, for example. The specification also fails to provide guidance for detecting active PAI-1 in these types of samples.

It is also known that not all proteins can be detected in all types of body fluid samples. For example, D'Amico et al. ("Pathophysiology of proteinuria" Kidney International, Vol. 63 (2003), pp. 809–825) teach that under normal conditions only a fraction of proteins of intermediate molecular weight are secreted in urine, while high molecular weight proteins are almost completely restricted from urine (see in particular p. 809, left column, the last four lines and right column, lines 1-7; p. 811, right column, first paragraph and p. 814, right column, the section "Increased transglomerular passage and urinary excretion of intermediate and HMW proteins", lines 6-13; p. 817, right column, the section "Renal tubular handling of an abnormal load of filtered proteins", lines 1-4).

Therefore, due to the state of the prior art, which fails to teach that the PAI-1/multimeric vitronectin complex is expressed and may be detected in whole blood, saliva, amniotic fluid, cerebrospinal fluid, all types of tissue extracts, and urine, the lack of direction/guidance presented in the specification regarding detection of active PAI-1 in these types of biological fluid samples, the lack of working examples directed to same, and the breadth of the claims, the specification fails to provide sufficient guidance to enable a skilled artisan to make and use the claimed invention in its full scope.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: a correlation step describing how the measurement of PAI-1/multimeric vitronectin relates back to the method objective recited in the preamble (determination of active PAI-1). While the claim recites that the complex is measured "to determine active PAI-1", this appears to be a restatement of the method objective and not an active method step in which the method objective is achieved. Either a correlation step or alternatively, active method steps may be recited that clearly relate back to the preamble.

9. Claim 5 recites the limitation "the PAI-1/multimeric vitronectin/first antibody/second antibody complex" in part (b). There is insufficient antecedent basis for this limitation in the claim as there is no prior mention of such a complex.

10. Claim 23 recites the limitation "the second antibody" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claim 1 does not recite a second antibody. For the purposes of examination claim 23 has been assumed to depend from claim 3.

11. Claim 23 recites that the second antibody is labeled with "biotin/avidin." The claim is indefinite because it is unclear whether the "biotin/avidin" is meant to indicate biotin OR avidin,

the combination of biotin AND avidin, etc. It is unclear what is being denoted by the slash ("/") in this term.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Lawrence et al. (*Journal of Biological Chemistry* (1997) **272**:7676-7680), or alternatively by Lawrence et al. (WO 97/39028, of record), which contains similar teachings. The citations below refer to the former document.

Lawrence et al. teach a method for determining active PAI-1 in a biological fluid. In particular, Lawrence et al. teach measuring the amount of PAI-1 bound to vitronectin in a sample of biological fluid (see in particular p. 7677-7678, "Assays for PAI-1 Binding for Vitronectin" and "Competitive Inhibition of PAI-1 Binding to Immobilized Vitronectin by Solution-phase Vitronectin"; and Figures 1 and 3 in particular). The PAI-1 measured is active (see p. 7678, "Results and Discussion", lines 9-11 in particular and p. 7677, right column, "Assays for PAI-1 Binding for Vitronectin" at the first paragraph). The biological fluid in this case is the liquid sample in the microtiter plates in which the reaction takes place. Lawrence et al. teach measuring the amount of PAI-1 bound to both monomeric vitronectin and to urea-purified vitronectin,

which is multimeric (see p. 7678, "Results and Discussion"; and also the instant specification at p. 8, lines 18-20).

14. Claims 1-2, 4, 6-8, 10, 14, 23-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Preissner et al. (*Blood* **74**:1989-1996 (1999)).

Preissner et al. teach a method comprising measuring the amount of PAI-1/multimeric vitronectin complex in a biological fluid sample (see p. 1992-1993, "Complex formation between vitronectin and plasminogen activator inhibitor-1 in platelet release" and p. 1990, "Assay Methods").

Although Preissner et al. do not specifically recite that *active* PAI-1 is determined, this would inherently be the case since the method measures PAI-1 that is bound to vitronectin, which is active PAI-1 (see the instant specification at p. 2, lines 15-20).

With regard to claims 2, 4 and 23, Preissner et al. teach contacting the biological fluid sample (platelet Ca-ionophore releasates in this case) with a first antibody that binds selectively to PAI-1 (PAI-1 monoclonal antibodies) and a labeled second antibody that binds selectively to multimeric vitronectin (polyclonal anti-vitronectin IgG that is labeled with biotin). The anti-vitronectin antibodies bound selectively to both dimeric and monomeric vitronectin (see Figure 3B and legend and p. 1991, right column, the first paragraph). Preissner et al. further teach determining the second antibody bound to the complex by incubating the labeled (biotinylated) second antibody with peroxidase-conjugated avidin (see p. 1990, right column, the third full paragraph in particular). See also Figure 6.

While Preissner et al. fail to explicitly teach that the PAI-1/multimeric vitronectin/first antibody/second antibody complex was separated from the sample prior to determining the

second antibody, as in claim 4, it would be immediately apparent to one skilled in the art that the 96-well microwell plate was washed following addition of the second antibody in accordance with standard ELISA assay techniques. Such a washing step would separate the complex from the sample.

With regard to claims 6 and 8, the platelet releasate sample is contacted simultaneously with both the first and second antibodies in that both antibodies are bound to the complex at the time of detection.

With regard to claims 7 and 24, the PAI-1 monoclonal antibodies were immobilized (coated) onto a solid support (96-multiwell plates). These plates would be considered to be an ELISA plate since they are plates upon which the ELISA assay is carried out (see p. 1990, the first paragraph of "Assay methods").

With regard to claim 10, Preissner also teach a method wherein the second antibody is non-biotinylated polyclonal anti-vitronectin IgG, and wherein the 96-microwell plate is instead contacted with peroxidase-conjugated swine (antirabbit) IgG that binds to the second antibody; in this embodiment, the peroxidase-labeled third antibody is then determined (see p. 1990, right column, the third full paragraph in particular).

With regard to claim 14, the platelet Ca-ionophore releasates were extracted from blood tissue. Preissner et al. further teach that ELISA method can be used for platelet releasates and lysates and for other biological fluids (p. 1990, left column, "Platelet preparation and aggregation", "Preparation of platelet releasate" and "Assay Methods").

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claims 3, 5, 9, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Preissner et al. in view of Harlow et al. (Antibodies: A Laboratory Manual (1988), Cold Spring Harbor Laboratory, Cold Spring Harbor, NY, pages 555-559, 561-562, 278-581, 583, 591-592, and 605).

Preissner et al. is as discussed above, which fails to specifically teach a method wherein the first antibody binds selectively to multimeric vitronectin and the labeled second antibody binds selectively to PAI-1; the converse is taught in Preissner et al.

Harlow et al. teach that in methods of detecting and quantitating antigens using a two-antibody sandwich assay, the choice of which antibody to label is determined empirically, and

that both combinations of solid-phase and labeled antibody should be tried to determine which is best (p. 580, item 1).

While Preissner et al. fail to explicitly teach that the PAI-1/multimeric vitronectin/first antibody/second antibody complex was separated from the sample prior to determining the second antibody, as in claim 5, it would be immediately envisaged by one skilled in the art that the 96-well microwell plate was washed following addition of the second antibody in accordance with standard ELISA assay techniques (see for example Harlow et al. at p. 579, second paragraph and p. 581, step 11 and the boldfaced text that follows). Such a washing step would separate the complex from the sample.

Therefore, it would have been obvious to one of ordinary skill in the art to employ the anti-vitronectin antibody as the solid phase antibody and the anti-PAI-1 antibody as the labeled antibody in the method of Preissner et al. because Harlow et al. teach that both combinations should be tried in order to determine which is best in a two-antibody sandwich assay method, such as that of Preissner et al.

18. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Preissner et al. in view of Forrest et al. (US 4,659,678).

Preissner et al. is as discussed above, which teaches a method wherein active PAI-1 is determined using a first antibody that binds selectively to PAI-1and a labeled second antibody that binds selectively to multimeric vitronectin, but which fails to teach a method wherein the first antibody *is attached to one member of a capture pair* and in which the sample-first antibody-second antibody mixture is contacted with a solid support *on which is immobilized the other member of the capture pair.*

Forrest et al. teaches methods of immobilizing antibodies to solid phase supports for use in immunoassays. In particular, Forrest et al. teach sandwich-type immunoassays using two antibody reagents, in which one of the antibodies is labeled and in which the other is non-covalently bound to a solid phase support (column 2, line 44 to column 3, line 68). The solid phase-bound antibody may be bound by use of a specific binding protein such as avidin or biotin, which constitute a very rapid, high affinity binding system, or by use of a third antibody directed against a reagent such as FITC that is attached to the antigen antibody; the third antibody is first linked to the solid support and then used to capture the antigen antibody (column 2, lines 52-58; column 4, line 55 to column 5, line 20). Forrest et al. further teach that the antigen is contacted with both antibodies prior to the addition of the solid phase component (see in particular column 5, lines 28-34 and column 8, lines 43-55).

Therefore, it would have been obvious to label the first antibody with avidin or biotin for immobilizing to the solid support in the method of Preissner et al. because Forrest et al. teach that such specific binding proteins constitute a very rapid, high affinity binding system for immobilizing antibodies to solid supports. It would have been further obvious to contact the sample with the first and second antibodies and then to contact the mixture with the solid support with bound avidin or biotin because Forrest et al. teach that this is preferable. One would have a reasonable expectation of success because Forrest et al. is also drawn to sandwich-type solid phase immunoassays employing two antibodies directed to distinct epitopes of an antigen.

19. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Preissner et al. in view of Harlow et al. as applied to claims 3, 5, 9, and 11 above, and further in view of Forrest et al. (US 4,659,678).

Preissner et al. and Harlow et al. are as discussed above, which teach a method wherein active PAI-1 is determined using a first antibody that binds selectively to multimeric vitronectin and a labeled second antibody that binds selectively to PAI-1, but which fail to teach a method wherein the first antibody *is attached to one member of a capture pair* and in which the mixture of sample-first antibody-second antibody is contacted with a solid support *on which is immobilized the other member of the capture pair.*

As discussed above, Forrest et al. teaches sandwich-type immunoassays using two antibody reagents, in which one of the antibodies is labeled and in which the other is non-covalently bound to a solid phase support (column 2, line 44 to column 3, line 68). The solid phase-bound antibody may be bound by use of a specific binding protein such as avidin or biotin, which constitute a very rapid, high affinity binding system, or by use of a third antibody directed against a reagent such as FITC that is attached to the antigen antibody; the third antibody is first linked to the solid support and then used to capture the antigen antibody (column 2, lines 52-58; column 4, line 55 to column 5, line 20). Forrest et al. further teach that the antigen is contacted with both antibodies prior to the addition of the solid phase component (see in particular column 5, lines 28-34 and column 8, lines 43-55).

Therefore, it would have been obvious to label the first antibody with avidin or biotin for immobilizing to the solid support in the method of Preissner et al. and Harlow et al. because Forrest et al. teach that such specific binding proteins constitute a very rapid, high affinity binding system for immobilizing antibodies to solid supports. It would have been further obvious to contact the sample with the first and second antibodies and then to contact the mixture with the solid support with bound avidin or biotin because Forrest et al. teach that this is preferable.

One would have a reasonable expectation of success because Forrest et al. is also drawn to sandwich-type solid phase immunoassays employing two antibodies directed to distinct epitopes of an antigen.

20. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Preissner et al. in view of Sigurdardottir et al. ("Studies on the interaction between Plasminogen Activator Inhibitor-1 and Vitronectin" (1992) Fibrinolysis 6:27-32).

Preissner et al. is as discussed above, which fails to specifically teach detection of the PAI-1/multimeric vitronectin complex in whole blood, plasma or serum.

Sigurdardottir et al. teach that PAI-1 is also found complexed to vitronectin in plasma and that increased levels of PAI-1 in plasma appear to be connected with thrombotic disease and may be a risk factor for recurrent myocardial infarction.

Therefore, it would have been obvious to one of ordinary skill in the art to employ the method of Preissner et al. with plasma samples because Sigurdardottir et al. teach that PAI-1 may be a marker of thrombotic disease and/or recurrent myocardial infarction. One would have reasonable expectation of success in detecting the complex in plasma because PAI-1 is also found complexed to vitronectin in plasma, as taught by both Sigurdardottir et al. and Preissner et al. (see Preissner et al. at p. 1995, right column).

21. Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Preissner et al. in view of Harlow et al. as applied to claim 3 above, and further in view of Ehrlich et al. (US 5,665,548).

Preissner et al. and Harlow et al. are as discussed above, in which the second antibody is indirectly labeled with peroxidase (via biotin-avidin interaction), but which fail to specifically teach that the second antibody is *directly* labeled.

Ehrlich et al. teach that in sandwich immunoassays, it is well known in the art that the labeled antibody may be labeled with a directly or indirectly detectable label, and that either is suitable so long as it allows for the detection of the antibody when bound to a solid support (column 27, line 39 to column 28, line 10). Ehrlich et al. teach that a preferred direct label is an enzyme, conjugated to the antibody, which produces a color reaction, such as horseradish peroxidase (column 27, lines 47-50).

Therefore, it would have been obvious to one of ordinary skill in the art to directly rather than indirectly label the second antibody with the peroxidase label in the method of Preissner et al. and Harlow et al., because Ehrlich et al. teach that indirect and direct labels are both suitable for sandwich immunoassays, which is the assay format used by Preissner et al. and Harlow et al.

22. Claims 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Preissner et al. in view of Harlow et al. as applied to claim 3 above, and further in view of Valenzuela et al. (US 6.428,792 B1).

Preissner et al. and Harlow et al. are as discussed above, in which the second antibody is labeled with biotin, but which fail to specifically teach that the label is a fluorophore or a luminescent material.

Valenzuela et al. teach that antibody labels known in the art also include fluorophores such as rhodamine and luminescent materials such as acridinium ester compounds (column 3, line 58 to column 4, line 7).

Therefore, it would have been obvious to one of ordinary skill in the art to employ a fluorophore such as rhodamine or a luminescent material such as an acridinium ester as taught by Valenzuela et al. in the method of Harlow et al. because Valenzuela et al. teach that such compounds are commonly known antibody labels for use in immunoassays for detection of immunocomplexes.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Foster whose telephone number is (571) 272-8786. The examiner can normally be reached on M-F 8:30-5. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached at (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christine Foster, Ph.D.
Patent Examiner
Art Unit 1641

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
01/09/06